DEC - 8 2000

Davol Inc.
Subsidiary of C. R. Bard, Inc.
100 Sockanossett Crossroad
P.O. Box 8500
Cranston, RI 02920
401. 463-7000

K 003674

DAVOL

6.0 510(k) Summary of Safety and Effectiveness for Nezhat-Dorsey™ Reusable Electrosurgical Attachments

A. Submitter Information

Submitter's Name:	Davol, Inc. Subsidiary of C. R. Bard, Inc.
Address:	100 Sockanossett Crossroad Cranston, RI 02920
Telephone:	401-463-7000 ext. 2529
Fax:	401-463-3845
Contact Person:	Ruth C. Forstadt
Date of Preparation:	November 1, 2000

B. Device Name

Trade name:	Nezhat-Dorsey™ Reusable Electrosurgical Attachments
Common/Usual Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories

C. Predicate Device Name

Unipolar Coagulator System, K911274 (Davol Inc.)

D. Device Description

Nezhat-Dorsey™ Reusable Electrosurgical Attachments consist of a distal partially insulated metal tip attached to a metal tube connected at the proximal end to the probe base. The probe base has fins for easy one-handed rotation and orientation of the tip. An extendible sheath encloses the metal tube. The sheath may be removed for cleaning and sterilization purposes. The unipolar high frequency cord is attached to the vertical multilam plug. The proposed device can be used with the Nezhat-Dorsey™ Trumpet Valve, Nezhat-Dorsey™ SmokEvac Trumpet Valve and Davol Trumpet Valve handles. The device is 5mm/33cm in length with the following electrode tip configurations: Corbitt Spatula tip, J-Hook tip, L-Hook tip, Ball tip and Needle tip. The Nezhat-

Dorsey™ Reusable Electrosurgical Attachment will be supplied non-sterile and must be sterilized prior to use.

E. Intended Use

Nezhat-Dorsey™ Reusable Electrosurgical Attachments are intended for evacuation of body fluids and electrosurgical cutting/coagulation during general laparoscopic procedures (e.g. laparoscopic cholecystectomy, appendectomy and herniorrhaphy). They are not intended for use in hysteroscopy or for contraceptive coagulation of the fallopian tube.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use.

The Nezhat-Dorsey™ Reusable Electrosurgical Attachment conforms to conventional industry standards and technology with regard to indication, materials, and theory of operation.

Nezhat-Dorsey™ Reusable Electrosurgical Attachments have the same indications for use as the predicate device in that they are indicated for evacuation of body fluids and electrosurgical cutting/coagulation during general laparoscopic procedures. Components of the proposed device are made from materials and design similar to the predicate device, and all materials are either used in the current reusable product or other commercially available Davol medical products. All materials are biocompatible. The proposed device has similar technological characteristics and fundamental scientific technology as the current reusable electrosurgical attachments. Both the modified Nezhat-Dorsey™ Reusable Electrosurgical Attachments and the current device contain a sheath to protect the patient from possible tip harm while orientating, and a quick-disconnect base for easy attachment to the trumpet valve.

Differences include the stiffer sheath, the fin design to the probe base, two new tip configurations that have been added to the present line of tips, and a change to the tip welding location on the tube. However, these differences are not significant and do not raise any new safety and effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 5 2001

Davol, Inc.
c/o Mr. Robert Mosenkis
President
CITECH, Inc.
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462

Re: K003674
Trade/Device Name: Nezhat-Dorsey™ Reusable Electrosurgical Attachments
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: November 28, 2000
Received: November 29, 2000

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of December 8, 2000, regarding the address.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003674

Device Name: Nezhat-Dorsey™ Reusable Electrosurgical Attachment

Indications for Use:

These instruments are intended for evacuation of body fluids and electrosurgical cutting/coagulation during general laparoscopic procedures (e.g. laparoscopic cholecystectomy, appendectomy and herniorrhaphy). They are not intended for use in hysteroscopy or for contraceptive coagulation of the fallopian tube.

(Please do not write below this line – Continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhersen

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K003674